

Food allergen labeling in the USA and Europe

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Purpose of review

The ingredient statement on the label of packaged foods is an important source of information for food-allergic consumers. New legislation in the USA and European Union will increase the amount of information available to food-allergic consumers.

Recent findings

The USA has implemented the Food Allergen Labeling & Consumer Protection Act, which mandates use of clear labeling and source labeling of ingredients derived from commonly allergenic sources. Similarly, the European Union is implementing new regulations that mandate the source labeling of ingredients derived from commonly allergenic foods and fuller disclosure of allergenic food components, even when present in small amounts. The food industry is providing consumers with information relating to the presence of allergenic residues by adding voluntary advisory statements, such as 'may contain peanuts'.

Summary

Food-allergic consumers are advised to follow specific strict avoidance diets that exclude allergenic foods and ingredients derived from these foods. Thus individuals must avoid potentially hazardous residues of the allergenic food that might occur as the result of common practices in the food industry. The ingredient statement on packaged food labels now contains more information than ever before.

Keywords

food allergy, ingredient, labeling, quality-of-life, regulation

Introduction

IgE-mediated food allergies affect an estimated 3.5–4% of the US population [1], with higher prevalence estimates of 5–8% among infants [2]. Prevalence estimates appear to be generally similar in Europe [3,4]. To a greater or lesser extent, all of these individuals must avoid the foods that elicit their allergic reactions. The ingredient statement on the label of packaged foods is a key source of information for allergic consumers. However, it should always be remembered that many of the most serious allergic reactions occur in restaurants and other food-service establishments [5,6] where full label disclosure of ingredients is typically not practiced.

Avoidance diets

Specific avoidance diets are an effective approach to the prevention of allergic reactions. If allergic to peanuts, for example, simply do not eat them. However, the implementation of safe and effective avoidance diets can be a daunting task for consumers with food allergies [7,8]. These individuals are often poorly prepared to face the challenges involved with the strict adherence to avoidance of specific food(s). Several key questions arise in the construction of safe and effective avoidance diets. These include: do threshold doses exist for the offending food or food ingredients? Will exposure to low levels of the offending food or allergenic proteins derived from it provoke allergic reactions? Will all ingredients made from the offending food pose a threat to the health of these individuals? Are there any likely hidden sources of exposure to the offending food?

Threshold or minimal eliciting doses likely exist for allergenic foods, although limited clinical data are available except for peanut, egg, and milk [9,10]. Evidence indicates that individual threshold doses can vary by several orders of magnitude from low milligram levels up to several grams of the offending food [9]. In controlled challenge trials, doses near the patient's individual threshold dose generally have provoked rather mild adverse reactions [10]. While exposure to low levels of allergenic foods or proteins derived from allergenic foods definitely presents a hazard, great individual variability exists suggesting that greater care must be taken in avoidance diets by some individuals compared to others with the same food allergy. Additionally, threshold doses appear to exist below which few, if any, individuals would experience noticeable adverse reactions. However, no consensus yet exists regarding such threshold levels

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Abbreviation

FALCPA Food Allergen Labeling & Consumer Protection Act

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and labeling regulations are not yet guided by threshold considerations.

The level of risk posed by ingredients derived from allergenic sources is predicated upon the amount of allergenic protein present in the ingredient, the nature of the protein in the ingredient, and the usage levels of the ingredient in food formulation. Some ingredients contain extremely low levels of protein. For example, highly refined oils from allergenic sources such as peanut and soybean do not pose a risk to the majority of peanut- or soybean-allergic individuals because the level of residual protein in the oils is extraordinarily low [11,12]. Some ingredients contain hydrolyzed or fermented proteins from the allergenic source. Extensively hydrolyzed proteins are likely safe for the majority of allergic consumers, while partially hydrolyzed proteins are more hazardous. The experience with infant formulas based on extensively or partially hydrolyzed milk proteins serves as evidence of the higher risk posed by partial hydrolysates [13]. Of course, a few milk-allergic infants even react adversely to extensively hydrolyzed casein formula which emphasizes the variability of individual responses [14]. The usage levels of the ingredient are also an important factor. Again, the formula experience must be considered in light of the fact that this is the sole source of nutrition for the infants. Other food uses of hydrolysates can involve much lower levels of exposure.

Other ingredients are made from commonly allergenic sources and contain low levels of residual protein although not as low as the edible oils. Examples include wheat starch, lactose, and soybean lecithin. Clinical challenge studies have not been done to clearly establish the allergenicity of these ingredients. Some patients avoid these ingredients while others do not. These ingredients are evidently safe for some individuals with allergies to the ingredient source but their safety for the entire population of such individuals has not been established. Of course, the level of use is again important and variable for these ingredients.

Ingredients derived from known allergenic sources can be considered as hidden ingredients if they are not declared on the label of the product [8]. However, other sources of hidden ingredients may be even more important based upon potential consumer exposure levels. The use of shared equipment and facilities, the adventitious presence of allergenic contaminants in raw materials, and packaging and formulation errors can lead to rather significant levels of hidden allergens in some cases [15^{••},16^{••}].

Physicians, dietitians, and other medical/nutrition professionals can play a pivotal role in providing useful information to individuals with food allergies regarding the establishment of safe and effective avoidance diets.

The quality of this educational advice and the success of individual food-allergic consumers in establishing proper avoidance diets are variable. Obviously, these consumers must rely upon the information presented on food labels to make wise choices. These consumers and the medical professionals who advise them must be able to understand and interpret information on food labels. This review is intended to provide accurate information on food-labeling practices in the USA and Europe, although similar approaches are also being implemented in other countries.

Food ingredient statements

In both the USA and the European Union, regulations require that the labels of packaged foods contain ingredient statements that list the components of the food. The ingredients must be listed in descending order of predominance. Given this general requirement, why is it so difficult to implement safe and effective avoidance diets? Regulations allow certain ingredients to be identified collectively; for example, natural and artificial flavors. In addition, the source of some ingredients is not readily apparent from the name that is designated on the ingredient statement. For example, a consumer might not recognize, until educated, that casein and whey are milk-derived ingredients that must be avoided by those allergic to milk. Furthermore, the sources of some ingredients may not necessarily be clear. Lecithin might be listed on an ingredient statement without revealing the source, which could be soybean, egg, rice, or sunflower seeds. Finally, only intentional ingredients must be declared on the ingredient statement so adventitious ingredients that might be present from various industry practices such as the use of shared processing equipment are often not identified. With the enactment of new regulatory requirements in both the USA and the European Union, many of these potentially confounding factors have been addressed.

The US Food Allergen Labeling & Consumer Protection Act

The US Congress has enacted a new labeling law [the Food Allergen Labeling & Consumer Protection Act (FALCPA)] that came into effect on January 1, 2006. Foods packaged after that date must adhere to the provisions of the new law so there will be a potentially awkward transitional period where foods packaged before and after that date will be on the market at the same time. Many of the provisions of FALCPA will benefit food-allergic consumers by requiring a clearer presentation of the ingredient information. The FALCPA addresses the most commonly allergenic foods in the USA and ingredients derived from those foods. The FALCPA recognizes milk, eggs, fish, crustacean shellfish (shrimp, prawns, crab, lobster), peanuts, soybeans, wheat, and tree nuts (almonds, walnuts, etc.) as the most common allergenic foods. The

new law requires the use of 'plain English language' to identify the sources of ingredients derived from commonly allergenic sources. For example, casein and whey must now be identified as from milk and semolina must be identified as from wheat. Any ingredients derived from these commonly allergenic sources must now be revealed on the ingredient statement. So, if the lecithin is derived from soybeans or eggs, then these sources will be identified. If no source is identified for lecithin, then presumably the lecithin is derived from another source such as sunflower seed or rice. Another example is starch, which in the USA is usually derived from corn. Corn starch could continue to be declared simply as starch. However, if the starch is derived from wheat, then this source has to be revealed on the ingredient statement. Collective declaration of certain ingredients – such as natural and artificial flavors – is still allowed but any allergenic sources contained within such ingredients must be revealed. The only exclusion from these provisions is highly refined oil, which need not be declared by source. However, the source of oils in many products is already declared on ingredient statements. This exclusion does mean that the presence of highly refined oil in a flavoring would not need to be declared.

The presence of commonly allergenic foods or ingredients derived from such foods can be provided in one or more ways: (1) the ingredient can simply be identified on the ingredient list, for example peanuts, wheat starch, soy lecithin; (2) the source of the ingredient can be identified parenthetically in the ingredient list, for example natural flavor (milk), lecithin (soy), casein (milk); or (c) a 'contains' statement can be used immediately below the ingredient statement, for example 'Contains: milk, peanut and soybean'. When a 'contains' statement is used, it may not always be easy to determine the ingredient that is derived from the identified allergenic source. For example, is the soy listed in the 'contains' statement because of the use of soy lecithin or the use of soy in the natural flavor, or both?

Concerns with the Food Allergen Labeling & Consumer Protection Act

Much more information will now be available to food-allergic consumers in the USA. Some of the increased information will be beneficial because it will help to prevent serious errors in avoidance diets, such as the ingestion of casein by milk-allergic consumers. However, the labeling of all ingredients derived from commonly allergenic sources (except highly refined oils) could conceivably lead to the identification of many ingredients that contain very low amounts of protein or allergen. In many cases, the evidence documenting the allergenicity of such ingredients is lacking. Even in cases where evidence exists to indicate that the ingredient is not allergenic, its declaration may still be required. Furthermore, FALCPA does not

Table 1 Ingredients derived from commonly allergenic sources

Allergenic source	Ingredient	Relative allergenicity
Milk	Casein	High
	Whey	High
	Lactose	Low
	Butter acids	Very low
Egg	Albumen	High
	Lysozyme	Moderate
Fish	Fish gelatin	Very low
	Isinglass	Very low
Soybean	Soy protein isolate	High
	Lecithin	Low
	Soy protein hydrolysate	Variable
Wheat	Wheat protein isolate	High
	Semolina	High
	Wheat starch	Low

exclude labeling of ingredients derived from allergenic sources that are used merely as processing aids. Processing aids are substances used to aid in the manufacturing of food but that have no technical or functional effect in the finished food product. Although US food-labeling requirements have always been reasonably thorough, the declaration of processing aids was not previously required. For example, soybean lecithin or wheat starch may be used as processing aids to prevent food from sticking to processing surfaces. The exposure to allergens from such uses would be quite low.

Table 1 contains a partial list of ingredients derived from commonly allergenic sources along with our assessment of their relative allergenicity (admittedly sometimes based on limited evidence). While the allergenicity of casein, whey, semolina, and soy protein isolate is well established, the level of allergenic proteins in other ingredients (for example, wheat starch, soy lecithin, and lactose) is much lower. Few allergic reactions have been documented from the use of these ingredients in foods [17–19] and most milk-allergic infants have been documented to tolerate lactose ingestion [20]. While fish gelatin and isinglass are primarily composed of proteins derived from fish, collagen is the principal protein in these ingredients while parvalbumin is the major fish allergen [21]. Fish gelatin was demonstrated to be safe for the vast majority of fish-allergic subjects at doses up to 1 g or more in a double-blinded, placebo-controlled oral challenge study [22]. The identification of allergenic sources for many of these ingredients could lead to serious restriction of the diets of allergic consumers. For example, soy lecithin is widely used as a processing aid in the bakery industry. The necessity of excluding most bakery products from the diets of soy-allergic consumers is definitely questionable.

The FALCPA does provide for notification and petition processes that could lead to the exclusion of labeling requirements for some ingredients. The notification

process is only available in situations where the absence of protein from the allergenic source can be documented. With the sensitivity of protein assays, this may not be practically possible. The petition process will likely require some evidence to support arguments of an absence of risk. That could be possible in cases such as fish gelatin but experience with the requirements of the US Food and Drug Administration for such petitions clearly needs to emerge over time.

Other potentially confounding issues exist with respect to implementation of the FALCPA. The US Congress did not define the term highly refined oil, so the labeling status of some oils may be subject to regulatory interpretation. More importantly, the FALCPA requires the designation of the species on labels for fish, crustacean shellfish, and tree nuts. While this provision makes sense for principal components (is it cod or salmon?), it creates potential confusion with certain ingredients. For example, fish gelatin is made from the skins of multiple species of fish. So, instead of fish gelatin, it might be cod, flounder, haddock, or red drum gelatin. Finally, the FALCPA does not identify the commonly allergenic tree nuts. So, does it include kola nut and nutmeg? From an allergenicity perspective, it should not, but these ingredients are indeed tree nuts. The US Food and Drug Administration may yet clarify some of this confusion.

The European situation

New food-labeling legislation came into effect in the European Union in November 2005. Previously, European countries recognized the so-called 25% rule which exempted the labeling of the ingredients in any food component (e.g. meatballs in pasta with meatballs) that comprised less than 25% of the formulation. The new legislation changes the 25% rule to a 5% rule, but also requires labeling of any commonly allergenic food or ingredient derived from that food even if present at less than 5% [16**]. Clearly, the elimination of the 25% rule exemption will benefit allergic consumers. In the European Union, the major allergens are milk, egg, fish, crustacean shellfish, peanuts, soybeans, tree nuts, cereals containing gluten (wheat, rye, barley, oats, spelt, and their hybridized strains), celery, mustard, and sesame seeds. Recent efforts are underway in the European Union to consider the addition of other foods, namely lupin and molluscan shellfish (oysters, clams, etc.) to the list of commonly allergenic foods. As in the USA, all ingredients derived from commonly allergenic foods must be declared on the label regardless of the level of use. No ingredients including highly refined oils were exempted from the legislation. However, the European Food Safety Authority has exempted fermentation substrates and their products including bacterial cultures and enzymes. The legislation also provided for an European

Food Safety Authority petition process to appeal for temporary or permanent exemptions from such labeling. An expert panel reviews the petitions and makes recommendations to the European Union regarding their acceptability. Thus far, temporary exemptions have been granted for several ingredients including highly refined soybean oil, wheat starch hydrolysate, and fish gelatin. The temporary exemptions were granted to provide petitioners with sufficient time to gather scientific/clinical data to support the lack of allergenic hazard of the ingredient. Decisions on permanent exemptions will be made upon completion and evaluation of this research. All ingredients that are not granted permanent exemptions will ultimately be included on the ingredient lists for foods packaged in the European Union.

Advisory labeling

The new labeling provisions in the USA and European Union relate only to intentionally added ingredients. As noted above, residues of allergenic foods may also occur adventitiously as the result of common food-industry practices such as the use of shared equipment. These practices can, on occasion, lead to potentially hazardous levels of allergenic residues resulting in severe allergic reactions [23,24]. The new legislation does not cover such adventitious presence even though such situations can and do present a greater risk than is posed by many of the intentional ingredients derived from allergenic sources. Increasingly, food companies in certain countries (USA, UK, Canada, Australia, and New Zealand) are providing consumers with advisory labeling statements to alert them to products that are subject to such adventitious contamination. The form of such labeling varies from country to country (Canada uses 'may contain' whereas the UK uses 'not suitable for nut allergy sufferers'). In the USA there is no standard form for such labeling but three different formats predominate: (a) 'may contain', (b) 'manufactured on shared equipment with', and (c) 'manufactured in shared facility with'. There is a popular misconception that the FALCPA outlaws such advisory labeling but it does not. Many companies who use such advisory labeling do so judiciously and only after assessing the potential risk. For these companies, there would always be some risk of an allergic reaction occurring in a consumer who ignores such labeling. In contrast, other companies appear to use advisory labeling more broadly, even in cases where the risk is virtually non-existent. While this situation might benefit from some regulatory standardization, allergic consumers should never be advised to ignore these statements on package labels. Advisory labeling decreases the food choices that can be made by a food-allergic consumer and this can have a serious impact on their quality of life. Thus, food companies should be urged to use advisory labeling only in situations where a risk to allergic consumers is plausible. But physicians should advise food-allergic patients to

avoid products with advisory labeling statements because many such products do represent an appreciable risk to such consumers.

Conclusion

There has been considerable recent change in food-labeling legislation in the USA and European Union. As a result, considerably more information will now be shared with allergic consumers. Avoidance diets will become much more restrictive if allergic consumers adhere to strict elimination of all foods containing even small amounts of ingredients derived from commonly allergenic sources. Basically, the onus for risk assessment has now been passed from food companies to allergic individuals. This new situation is bound to create confusion, consternation, and many questions among food-allergic individuals. Many of these questions will be posed to medical professionals. Are you ready?

Acknowledgements

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References and recommended reading

Papers of particular interest, published within the annual period of review, have been highlighted as:

- of special interest
- of outstanding interest

Additional references related to this topic can also be found in the Current World Literature section in this issue (p. 244).

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